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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re patent application of:) Before the Examiner
Joel S. Douglas) Christopher L. Chin
Serial No. 09/875,297)
Filed June 7, 2001) Group Art Unit
) 1641
)
) Our Ref. 018176-391
)
) December 10, 2003
DEVICE FOR DETERMINATION)
OF AN ANALYTE IN A BODY)
FLUID)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

December 10, 2003

(Date of Deposit)

Charles P. Schmal

Name of Registered Representative

Signature

December 10, 2003

Date of Signature

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicant requests consideration of the references listed on attached form PTO-1449 and/or the additional information identified below in paragraph 3. A legible copy of each reference listed on form PTO-1449 is enclosed, except:

☐ a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior parent application Serial No. _____ and/or

☐ a copy of each U.S. patent and/or U.S. patent application publication is not provided because the present application has been filed or entered the national stage after June 30, 2003 and the Patent Office has waived the requirements of 37 CFR 1.98 (a)(2)(i) for submitting such documents in applications filed or nationalized after June 30, 2003.

1a. ☐ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application (other than a continued prosecution application), or

before the mailing date of the first Office Action on the merits,

and thus no certification and/or fee is required.

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1b. ☒ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or Notice of Allowance, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☒ a fee of **\$180.00** (set forth in 37 CFR §1.17(p)) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance and prior to payment of the issue fee, and thus:

the certification of paragraph 2 below is provided, and

a fee of \$_____ (set forth in 37 CFR §1.17(p)) is enclosed.

2. It is hereby certified

a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, or

b. ☐ that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

c. ☐ A copy of a dated communication from a foreign patent office which clearly shows the statement is being submitted within three (3) months of the date on the communication is enclosed.

3. ☐ A copy of a Search Report or Written Opinion from a foreign patent office is enclosed.

4. ☐ Consideration of the following additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.



5.

For each non-English language reference listed on the attached form PTO-1449, reference is made to:

- a. ☐ an English language translation submitted herewith,
- b. ☐ a foreign patent office search report (in the English language) submitted herewith,
- c. ☐ an English language translation of a foreign patent office search report submitted herewith,
- d. ☐ the concise explanation contained in the specification of the present application at page^s _____,
- e. ☐ the concise explanation set forth in the attached English language abstract,
- f. ☐ a copy of a related patent publication (in the English language) submitted herewith,
- g. ☐ the concise explanation set forth below:

The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b).

It is believed that no additional fees are required. Should any other fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully Submitted,

Charles P. Schmal, Reg. No. 45,082
Woodard, Emhardt, Moriarty, McNett &
Henry LLP
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456



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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	09/875,297
				Filing Date	6/7/2001
				First Named Inventor	DOUGLAS, RADWANSKI, DUCHON, ET A
				Group Art Unit	1641
				Examiner Name	Christopher L. Chin
Sheet	1	of	6	Attorney Docket Number	7404-89

U.S. PATENT DOCUMENTS

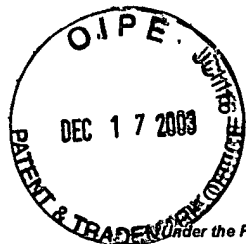
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		4,151,832	05-01-1979	Hamer	
		4,360,016	11-23-1982	Sarrine	
		4,503,856	03-12-1985	Cornell et al.	
		4,517,978	05-21-1985	Levin et al.	
		4,622,974	11-18-1986	Coleman et al.	
		4,648,408	03-10-1987	Hutcheson et al.	
		4,653,511	03-31-1987	Goch	
		4,653,513	03-31-1987	Dombrowski	
		4,658,821	04-21-1987	Chiodo et al.	
		4,678,757	07-07-1987	Rapkin et al.	
		4,685,463	08-11-1987	Williams	
		4,805,623	02-21-1989	Jobsis	
		4,826,759	10-04-1984	Guire et al.	
		4,850,973	07-25-1989	Jordan et al.	
		4,858,607	08-22-1989	Jordan et al.	
		4,873,993	10-17-1989	Meserol et al.	
		4,883,068	11-28-1989	Dechow	
		4,906,439	03-25-1986	Grenner	
		4,920,977	05-01-1990	Haynes	
		4,924,879	05-15-1990	O'Brien	
		4,953,552	09-04-1990	DeMarzo	
		4,976,724	12-11-1990	Nieto et al.	

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				Examiner Name	Christopher L. Chin
Sheet	2	of	6	Attorney Docket Number	7404-89

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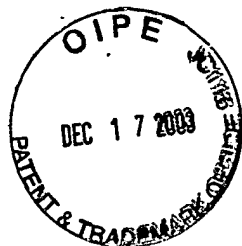
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
		4,994,068	02-19-1991	Hufnagle	
		4,994,167	02-19-1991	Shults et al.	
		4,994,238	02-19-1991	Daffern et al.	
		4,999,287	05-19-1988	Allen et al.	
		5,002,054	03-26-1991	Ash et al.	
		5,014,718	05-14-1991	Mitchen	
		5,029,583	07-09-1991	Meserol et al.	
		5,035,704	07-30-1991	Lambert et al.	
		5,054,499	10-08-1991	Swierczek	
		5,066,859	11-19-1991	Karkar et al.	
		5,070,886	12-10-1991	Mitchen et al.	
		5,073,484	03-09-1982	Swanson et al.	
		5,096,833	05-29-1990	Lau et al.	
		5,108,889	04-28-1992	Smith	
		5,163,442	11-17-1992	Ono	
		5,164,294	05-18-1988	Skold et al.	
		5,165,418	11-24-1992	Tankovich	
		5,178,831	06-03-1988	Sakota et al.	
		5,201,324	04-13-1993	Swierczek	
		5,202,268	04-13-1993	Kuhn et al.	
		5,217,480	06-08-1993	Haber et al.	
		5,223,220	03-27-1990	Fan et al.	

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				Examiner Name	Christopher L. Chin
Sheet	3	of	6	Attorney Docket Number	7404-89

U.S. PATENT DOCUMENTS

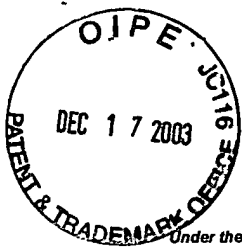
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		5,231,993	08-03-1993	Haber et al.	
		5,277,198	01-11-1994	Kanner et al.	
		5,318,583	06-07-1994	Rabenau et al.	
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		5,320,607	06-14-1994	Ishibashi	
		5,334,502	11-27-1991	Sangha	
		5,354,692	09-08-1992	Yang et al.	
		5,366,902	11-22-1994	Cox et al.	
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		5,395,387	03-07-1995	Burns	
		5,424,220	01-31-1992	Goerlach-Graw et al.	
		5,565,170	10-15-1996	Sakamoto	
		5,569,212	10-29-1996	Brown	
		5,582,184	12-10-1996	Erickson et al.	
		5,628,309	05-13-1997	Brown	
		5,628,764	03-21-1995	Schraga	
		5,638,828	06-17-1997	Lauks et al.	
		5,668,017	09-16-1997	Buchanan et al.	
		5,682,233	10-28-1997	Brinda	
		5,700,695	12-23-1997	Yassinzadeh et al.	
		5,710,049	06-04-1990	Noppe et al.	
		5,712,172	04-18-1995	Huang et al.	

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				First Named Inventor	DOUGLAS, RADWANSKI, DUCHON, ET AL
				Group Art Unit	1641
				Examiner Name	Christopher L. Chin
Sheet	4	of	6	Attorney Docket Number	7404-89

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		Number-Kind Code ² (if known)			
		5,725,831	03-10-1998	Reichler et al.	
		5,728,587	12-18-1989	Kang et al.	
		5,872,713	02-16-1999	Douglas et al.	
		6,162,639	12-19-2000	Douglas	
		D 254,444	03-11-1980	Levine	

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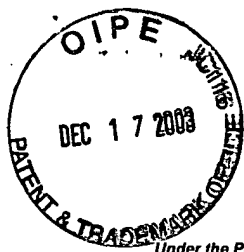
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				Examiner Name		Christopher L. Chin	
Sheet	5	of	6	Attorney Docket Number		7404-89	
FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite 1 No.	Foreign Patent Document Country Code ³ - Number ⁴ -Kind Code ⁵ (if known)		Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁶
		DE 37 08 031 A1		11-12-1987			<input type="checkbox"/>
		EP 0 852 336		07-08-1998			<input type="checkbox"/>
		WO 85/04089 A1		09-26-1985			<input type="checkbox"/>
		WO 95/10223 A2		04-20-1995			<input type="checkbox"/>
		WO 96/32635		11-09-1999			<input type="checkbox"/>
		WO 97/12242		04-03-1997			<input type="checkbox"/>
		WO 97/43962 A1		11-27-1997			<input type="checkbox"/>

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. 1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published			T²
		ASH ET AL., "Subcutaneous Capillary Filtrate Collector for Measurement of Blood Glucose", ASAIO Journal, 1992			<input type="checkbox"/>
		BRACE ET AL., "Re-evaluation of the Needle Method for Measuring Interstitial Fluid Pressure", American Journal of Physiology, 1975			<input type="checkbox"/>
		GINSBERG, "An Overview of Minimally Invasive Technologie", Clinical Chemistry, 1992			<input type="checkbox"/>
		JANLE-SWAIN ET AL., "Use of a Capillary Filtrate Collector for Monitoring Glucose in Diabetics", ASAIO Journal, 1987			<input type="checkbox"/>
		KAYASHIMA ET AL., "Suction Effusion Fluid from Skin and Constituent Analysis: New Candidate for Interstitial Fluid", American Journal of Physiology, 1992			<input type="checkbox"/>
		TURNER ET AL., "Diabetes Mellitus: Biosensors for Research and Management", Biosensors, 1985			<input type="checkbox"/>

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